E3

35. (Amended) The preconcentrate of claim 29, wherein the preconcentrate comprises grapefruit extract or a component thereof.

45. (Amended) A storage-stable, self-emulsifying, and non-aqueous preconcentrate of a taxane in a microemulsion comprising a taxane dissolved in a carrier system, which carrier system consists essentially of:

E4

10 to 80% w/w of a hydrophobic component;

20 to 80% w/w of a surfactant component; and

6% to 40% w/w of a hydrophilic component, at least a portion of which hydrophilic component consists of ethanol, such that the carrier system contains at least 6% w/w ethanol.

51. (Amended) A storage-stable, self-emulsifying, and non-aqueous preconcentrate of a taxane in a microemulsion comprising a taxane dissolved in a carrier system, which carrier system consists essentially of:

10 to 80% w/w of a hydrophobic component selected from the group consisting of a triglyceride, a diglyceride, a monoglyceride, a free fatty acid, a fatty acid ester, a fish oil, a vegetable oil, and combinations thereof;

E5

20 to 80% w/w of a surfactant component consisting of one or more surfactants selected from the group consisting of a polyoxyethylene-sorbitan-fatty acid ester, a polyoxyethylene fatty acid ester, a polyoxyethylene castor oil derivative, α-tocopherol, α-tocopheryl polyethylene glycol succinate, α-tocopherol palmitate, α-tocopherol acetate, a PEG glyceryl fatty acid ester, a propylene glycol mono- or di-fatty acid ester, a sorbitan fatty acid ester, a polyoxyethylene-polyoxypropylene co-polymer, glycerol triacetate, a monoglyceride, an acetylated monoglyceride, and combinations of any thereof; and

6% to 40% of a hydrophilic component, at least a portion of the hydrophilic component consisting of ethanol, such that the carrier system contains at least 6% w/w ethanol.

53. (Amended) An injectable pharmaceutically acceptable composition consisting essentially of a storage-stable, self-emulsifying, and non-aqueous preconcentrate of at least one taxane in a composition consisting essentially of:

E6

10 to 80% w/w of a hydrophobic component;

20 to 80% w/w of a surfactant component; and

6% to 40% w/w of a hydrophilic component,

wherein (a) at least a portion of which hydrophilic component consists of ethanol, such that the composition contains at least 6% w/w ethanol, (b) the surfactant component of the composition consists of one or more non-ionic surfactants, or (c) conditions (a) and (b) apply.

Add the following claims:

54. (New) A storage-stable, self-emulsifying, and non-aqueous, preconcentrate of a taxane in a microemulsion consisting of a taxane dissolved in a carrier system, which carrier system consists of:

10 to 80% w/w of a hydrophobic component selected from the group consisting of a triglyceride, a diglyceride, a monoglyceride, a free fatty acid, a fatty acid ester, a fish oil, a vegetable oil, and combinations thereof;

20 to 80% w/w of a surfactant component consisting of one or more non-ionic surfactants;

up to 35% w/w diethylene glycol monoethylether; and

up to 40% w/w of a hydrophilic component selected from the group consisting of a hydroxyalkane, a dihydroxyalkane, a polyethylene glycol having an average molecular weight of at most 1000, and combinations thereof;

wherein the preconcentrate, when mixed with water or simulated gastric fluid, forms a liquid having an average droplet size of at most 10 microns, and a dose of the preconcentrate has a taxane bioavailability of 25 to 60% of the taxane in the dose upon oral administration.

55. (New) A storage-stable, self-emulsifying, and non-aqueous preconcentrate of at least one taxane in a composition consisting of:

10 to 80% w/w of a hydrophobic component selected from the group consisting of a triglyceride, a diglyceride, a monoglyceride, a free fatty acid, a fatty acid ester, a fish oil, a vegetable oil, and combinations thereof;

20 to 80% w/w of a surfactant component consisting of one or more non-ionic surfactants; and

up to 40% of a hydrophilic component selected from the group consisting of a hydroxyalkane, a dihydroxyalkane, a polyethylene glycol having an average molecular weight of at most 1000, 1,2-propylene glycol, ethanol, and combinations thereof;
wherein the preconcentrate, when mixed with water or simulated gastric fluid, gives an average droplet size of at most 10 microns, and a dose of the preconcentrate has a taxane bioavailability of 25 to 60% of the taxane in the dose upon oral administration.

56. (New) A method of orally or parenterally administering a taxane to a subject in need of same consisting of administering a dose of a storage-stable, self-emulsifying, and non-aqueous preconcentrate of a taxane consisting of:

10 to 80% w/w of a hydrophobic component selected from the group consisting of a triglyceride, a diglyceride, a monoglyceride, a free fatty acid, a fatty acid ester, a fish oil, a vegetable oil, and combinations thereof;

20 to 80% w/w of a surfactant component consisting of one or more non-ionic surfactants; and

up to 40% w/w of a hydrophilic component selected from the group consisting of a hydroxyalkane, a dihydroxyalkane, a polyethylene glycol having an average molecular weight of at most 1000, and combinations thereof;

wherein the preconcentrate, when mixed with water or simulated gastric fluid, gives an average droplet size of at most 10 microns, and a dose of the preconcentrate has a taxane bioavailability of 25 to 60% of the taxane in the dose upon oral administration.

57. (New) A storage-stable, self-emulsifying, and non-aqueous preconcentrate of a taxane in a microemulsion consisting of a taxane dissolved in a carrier system, which carrier system consists of:

10 to 80% w/w of a hydrophobic component;

20 to 80% w/w of a surfactant component consisting of one or more non-ionic surfactants; and

up to 40% w/w of a hydrophilic component.